K061088

510(k) Summary

Honeywell HomMed Sentry OTC Monitor

Date: April 11, 2006

JUN - 9 2006

Consultant Contact: Tommie J. Morgan, Ph.D., President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008
713.880.5111 Voice or 713.880.3494 Fax

Company: Michael Leigh, Director Regulatory/Quality
Honeywell HomMed, LLC
3400 Intertech Drive, Suite 200
Brookfield, WI 53045
262.252.5794 Voice or 262.252.6119 Fax

Trade Name: Honeywell HomMed Sentry OTC Monitor

Common Name: Vital Signs Monitor

Classification Name: Cardiovascular and Respiratory Devices, Class II

Product Code: NIBP Measurement System, DXN

Predicate Device: HomMed Sentry IIIB Patient Monitor System K040651

Device Description: The Honeywell HomMed Sentry OTC Monitor is a vital signs monitoring system. The system measures noninvasive blood pressure, pulse rate, oral temperature and weight. The Sentry OTC Monitor has six serial ports available for external options. The Sentry OTC Monitor acquires the vital signs data and displays it. The data can be transmitted via the communication module to a central viewing station.

Indications for Use: *The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.*

Intended Use: The Honeywell HomMed Sentry OTC is the remarketing of a previously approved product for OTC use. It is intended for personal use and use of the system allows retrospective review of certain physiological functions. The Sentry OTC collects vital signs data (including noninvasive blood pressure, pulse rate, oral temperature, and weight) then can transmit the data to a central review station via a communication network. The Sentry OTC is intended for use with adult and pediatric patients over twelve years of age.

Technology: The Honeywell HomMed Sentry OTC Monitor employs the same technologies of the predicate device, HomMed Sentry IIIB Patient Monitor System, K040651.

The Honeywell HomMed Sentry Monitor(s) complies with the following voluntary standards:

- EN 60601-1 Medical Electrical Safety
- IEC 601-1-2 EMC Compliance
- ISO 10993-5,10-11 Biocompatibility

Test Summary: The Honeywell HomMed Sentry System (Sentry OTC and its predicate Sentry IIIB) utilized within the environments for which it is marketed performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. Completed EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing demonstrate compliance with applicable standards. The test results demonstrated that the Sentry is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

Conclusion: It is the Honeywell HomMed position that the results of these evaluations demonstrate the Sentry OTC Monitor is as safe, as effective and performs as well as the legally marketed predicate device, HomMed Sentry IIIB Patient Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

Honeywell HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008

Re: K061088
Trade Name: Honeywell HomMed Sentry OTC Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: April 12, 2006
Received: April 18, 2006

Dear Dr. Morgan:

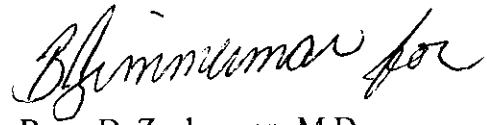
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061088

Device Name: Honeywell HomMed Sentry OTC Monitor

Indications For Use:

The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061088